

MANUFACTURING & LABELING CHECKLIST

FOR LOW & MODERATE RISK FOODS - PROCESS REVIEW INFORMATION

RETURN TO: MONTANA FOOD, DRUG & COSMETIC PROGRAM
 COGSWELL BLDG RM C214
 PO BOX 202951
 HELENA MT 59620-2951 Phone (406) 444-5306

The following questions should be answered about your product. If the question does not apply to your particular product write "N/A" and if not obvious, then tell why it does not apply. If you have questions about the meaning of some questions please feel free to call us at the above number. Low a risk foods include dry mixes, berry preserves, syrups, confections, baked goods, mustards, etc.

NAME OF MANUFACTURING/PROCESSING ESTABLISHMENT _____

NAME OF OWNER CORPORATION _____

CONTACT PERSON _____ EMAIL, IF ANY _____

STREET ADDRESS OF POINT OF MANUFACTURE _____

MAILING ADDRESS (if different) _____

CITY _____ STATE _____ ZIP _____

TELEPHONE # (____) - _____ FAX # (____) - _____

IS THIS PRODUCT INTENDED TO BE A: (Check one)

FOOD PRODUCT _____ DIETARY SUPPLEMENT _____ COSMETIC _____ DRUG / MEDICATION _____

COMMON NAME FOR THE PROPOSED PRODUCT _____
(i.e. - "Pancake mix")

YOUR TRADE NAME FOR THE PRODUCT _____
(i.e. - "Blue Mountain Buckwheat Pancake Mix")

IS THE PROCESSING CONFINED TO REPACKING? _____ YES _____ NO (Repacking is a process in which large containers of food are repacked into retail size packages, i.e. 100# sacks of beans repacked as 1# packages.)

WILL THERE BE ONSITE RETAIL SALES? _____ YES _____ NO

WILL THE PRODUCT BE SOLD WHOLESALE (*case lots*) FOR RE-SALE ELSEWHERE? _____ YES _____ NO

WHAT STORES WILL BE CARRYING THE PRODUCT _____

WILL THE PRODUCT BE SOLD VIA THE INTERNET? _____

WILL THE PRODUCT BE SOLD ONLY IN MONTANA? _____ OUTSIDE MONTANA (INTERSTATE) _____

INGREDIENTS IN DESCENDING ORDER OF PREDOMINANCE BY WEIGHT, AND THE WEIGHTS AND MEASURE OF EACH PER BATCH, IDENTIFYING BATCH SIZE.

BATCH SIZE _____

BATCH WEIGHT _____

INGREDIENT	MEASURE PER BATCH	WEIGHT PER BATCH
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

LIST ALL COMPONENTS THAT HAVE INGREDIENTS WITHIN THE INGREDIENTS IN PARENTHESES
Mayonnaise (egg yolks, vegetable oil, lemon juice, salt, vinegar, oxystearin...)

(A copy of page 2 is needed for each variation, including label exhibit. For example--one set for blueberry muffins, and another set for poppyseed muffins, and another for brownies, etc. Photocopy p. 2 as needed.)

ARE ANY RESTRICTED INGREDIENTS TO BE USED OR ALREADY IN YOUR PRODUCT (*Sulfites, sweeteners, MSG flavorings*)? YES _____ NO _____

LIST HERE _____

LIST ALL FOOD COLORINGS, WHETHER ADDED DIRECTLY OR CONTAINED WITHIN INGREDIENTS USED IN THE PRODUCT (*ingredients within ingredients*).

ARE ANY ORGANIC CLAIMS BEING MADE? YES _____ NO _____ IF YES, THEN ATTACH 3RD PARTY CERTIFICATION COPIES OR OTHER DOCUMENTATION.

ARE ANY OTHER CLAIMS BEING MADE SUCH AS "PURE", "NATURAL", "LIGHT", "LOW CHOLESTEROL", "LOW FAT", "REDUCED SALT", ETC? YES _____ NO _____ IF YES, THEN ATTACH DOCUMENTATION. IF A NUTRITIONAL CLAIM IS MADE, YOU MAY NOT USE THE EXEMPTION FROM NUTRITION FACTS LABELING.

IS NUTRITIONAL LABELING INFORMATION BEING INCLUDED? YES _____ NO _____ IF YES, THEN ATTACH DOCUMENTATION, OR EXPLANATION.

NOTE: Nutrition labels required after May 1994, with some exceptions - including small business producing less than 10,000 units last year and having fewer than 50 employees, if no label claims are made or implied. For further description of NLEA exemption see pp. 22-28 of the LABELING GUIDE, or call us at the number given above.)

WILL THE PRODUCT LABEL REQUIRE REFRIGERATION? YES _____ NO _____

WILL THERE BE AN "OUT DATE" OR "BEST IF USED BY ..." DATE? YES _____ NO _____
IF THE PRODUCT IS TO BE WHOLESALED (OFFERED AT OUTLETS AWAY FROM THE MANUFACTURING FACILITY, INCLUDE INFORMATION ON WHAT QUALITY CONTROL PROCEDURES YOU WILL USE.

MANUFACTURED FOOD SECTION

LOW ACID CANNED FOODS 1) Have pH greater than 4.6 and water activity greater than 0.85, 2) are sealed hermetic (*air-tight*) container, 3) receives a heat treatment for the purpose of achieving commercial sterility, 4) and is normally stored under non-refrigerated conditions.

AN ACIDIFIED FOOD is a low acid food to which acid(s) or acid food(s) are added. It has a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below. An acidified food is normally stored and distributed under non-refrigerated conditions. (*Carbonated soft drinks are not acidified foods.*)

IF YOU MEET EITHER OF THE ABOVE CRITERIA YOU MUST HAVE AN FDA APPROVED SCHEDULED PROCESS, APPROPRIATE TRAINING , AND YOU MUST REGISTER YOUR PRODUCT WITH THE FDA (*FOOD & DRUG ADMINISTRATION*). IF APPLICABLE ARE YOU REGISTERED WITH FDA?

N.A. _____ YES _____ NO _____

IF ACIDIFIED FOODS OR LOW-ACID FOODS ARE TO BE PRODUCED & PACKAGED, INCLUDING SALSA, DRESSINGS, SAUCES ETC., WITH A pH OF 4.5 OR ABOVE YOU SHOULD USE THE MONTANA PROCESS SCHEDULE FP114. INCLUDE LAB TEST RESULTS FOR pH.

DESCRIBE IN DETAIL YOUR MANUFACTURING PROCESS: INCLUDE TIMES, TEMPERATURES OF COOKING PROCESS IF APPLICABLE, SOURCE OF PRINCIPAL INGREDIENTS & ALSO DESCRIBE SET UP PROCEDURES, FINISHED PRODUCT HANDLING, CLOSURES, PRODUCTION CODES OR DATE CODES, SHELF LIFE, QUALITY CONTROL OR TESTING PROCEDURES ETC. (*Use additional sheets if necessary*)

PACKAGING MATERIAL, CONTAINER CLOSURES: (*describe*)

LABELS - MOST COUNTIES REQUIRE LABELING REVIEW & APPROVAL PRIOR TO LICENSING. AN ACTUAL SIZE LABEL EXHIBIT IS NEEDED FOR THIS PURPOSE. A CLEAR PHOTOCOPY WILL DO.

ATTACH PRINTERS PROOF OR PHOTOCOPY OF PROPOSED LABEL HERE , OR ON A SEPARATE SHEET. 

IF THIS IS A NEW FACILITY, HAVE YOU CONTACTED THE LOCAL HEALTH DEPARTMENT FOR APPROVAL AND INSPECTION OF YOUR FACILITY? YES _____ NO _____

NAME OF THAT DEPARTMENT _____

WHO DID YOU TALK TO THERE _____

DID YOU HAVE A CURRENT "Food Purveyor License" ISSUED BY THE DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES (FOOD & CONSUMER SAFETY)? YES _____ NO _____

IF YES, GIVE NAME ISSUED UNDER: _____

AND THE NUMBER OF THE LICENSE: F _____

AND THE ENDORSEMENT TYPE (F1, F2, F6, F13 ETC): _____

AND THE COUNTY IN WHICH LICENSE WAS ISSUED: _____

AND THE PRODUCT CODES APPROVED (IF ANY): _____

WATER BOTTLERS

IF YOUR PRODUCT IS WATER, HAVE YOU CONTACTED THE DRINKING WATER PERMIT SECTION OF THE MONTANA DEPARTMENT OF ENVIRONMENTAL QUALITY (DEQ)?

YES _____ NO _____ N/A _____

DATE _____ CONTACT PERSON _____

HAVE PLANS BEEN SUBMITTED TO THAT AGENCY AND APPROVED?

YES _____ NO _____ PWS NUMBER ISSUED _____

DESCRIBE THE SIZE OF CONTAINERS OR BOTTLES YOU WILL BE USING: _____

PRIOR APPROVAL AND A PWS NUMBER ARE REQUIRED PRIOR TO LICENSING. PRODUCTION CODING/DATE CODING ARE REQUIRED FOR BOTTLED WATER.

INCLUDE A SCHEMATIC OF THE WATER TREATMENT, CONTAINER STORAGE PLANS, BOTTLING EQUIPMENT, LABELS, COPIES OF THE CHEMICAL ANALYTICALS, AND OTHER DETAILS AS ATTACHMENTS TO THIS FORM.

IF YOU ARE PACKING OR BOTTLING WATER FROM A SOURCE OTHER THAN YOUR OWN (CO-PACKING FOR ANOTHER FIRM) THE ANALYTICALS FOR THEIR WATER MUST BE REVIEWED AND APPROVED PRIOR TO BOTTLING. IF YOU ARE BOTTLING YOUR WATER UNDER DIFFERENT SPONSOR LABELS, PLEASE INCLUDE LABEL EXHIBITS AS APPROPRIATE.

